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Registration Decision RD2013-18

Dried Eggs, Wintergreen Oil, Castrol Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids

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Registration Decision for Dried Eggs, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Dried Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray containing the active ingredients Dried Eggs, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids to prevent feeding damage to outdoor ornamental plants by white-tailed deer and black-tailed deer.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2012-33, *Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for Dried Eggs, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2012-33. This decision is consistent with the proposed registration decision stated in PRD2012-33.

For more details on the information presented in this Registration Decision, please refer to PRD2012-33, which contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What Are Dried Eggs, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture Capsaicin and Related Capsaicinoids?

Dried eggs, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids prevents feeding damage by white-tailed and black-tailed deer to outdoor ornamentals by combining both odour and taste repellents.

Health Considerations

Can Approved Uses of Dried Eggs, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids Affect Human Health?

Dried eggs, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are unlikely to affect your health when used according to label directions.

Exposure to dried eggs, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids may occur when handling and applying the products, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray, as well as during typical residential activities following application. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Eggs, fish, and garlic are known to cause allergic reactions in sensitive individuals. Precautionary statements alerting users of the potential for an allergic reaction in individuals sensitive to eggs, fish, and garlic are required on the product labels for both Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray.

Inhalation, dermal, and ocular exposures are possible when applying the product, particularly to the applicator and bystanders located near the treatment area. Also, entry into a recently sprayed area may result in dermal exposure. Therefore, spray advisory and restricted entry statements are required on the end-use product labels to minimize applicator and bystander exposures.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The use pattern of Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray do not include food or feed crops. The active ingredients are found in foods and consumer products and any residues that may occur in drinking water from the use pattern are not expected to pose a concern to human health.

Occupational Risks from Handling Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray

Occupational risks are not of concern when Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray are used according to label directions, which include protective measures.

Domestic users handling and applying Bobbex Deer Repellent Concentrate or Bobbex Deer Repellent Ready-To-Use Spray to areas that attract deer, such as trees, plants, shrubs, flowers, and non-flowering plants, can come in direct contact with the active ingredients on the skin and in the eyes. Following the precautionary label statements aimed at minimizing exposure to the product will ensure domestic users are appropriately protected. The potential for inhalation while handling and applying the product will be negligible when users observe the precautionary label statements.

Accidental bystander exposure is possible from spray drift, but exposure is expected to be negligible when the precautionary label statements are observed by the applicator.

Postapplication exposure is possible in individuals who immediately enter freshly treated areas. People who are allergic to eggs, fish or garlic should exercise precaution before entering freshly treated areas.

Environmental Considerations

What Happens When Dried Eggs, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids Are Introduced Into the Environment?

Dried eggs, wintergreen oil, castor oil, fish meal mixture, fish oil mixture, garlic oil, meat meal mixture, capsaicin and related capsaicinoids are expected to degrade rapidly in the environment. The active ingredients are food grade, and have a non-toxic mode of action (that is, they act as a repellent). Environmental exposure is expected to be minimal when the end-use products containing these active ingredients are used under the current domestic use pattern.

Value Considerations

What Is the Value of Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray?

Bobbex Deer Repellent Concentrate applied at a dilution of one part product to five parts water and Bobbex Deer Repellent Ready-To-Use prevents feeding damage to outdoor ornamentals by white-tailed and black-tailed deer by combining both odour and taste repellents. Both of these products are compatible with an Integrated Pest Management program to prevent deer damage to ornamental plants.

Confirmatory efficacy data were required testing Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use on herbaceous ornamental plants species to prevent feeding damage to outdoor ornamentals by white-tailed and black-tailed deer.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Dried Eggs, Bobbex Deer Repellent RTU Technical, Bobbex Deer Repellent Concentrate Technical, Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray to address the potential risks are as follows.

Key Risk-Reduction Measures

Human Health

The statement, "Warning, contains the allergen egg", has been included on the principal display panel of the technical product label for Dried Eggs and "Warning, contains the allergen fish" on the principal display panel of the technical product labels for each of the technical products. The statements, "DANGER – EYE IRRITANT", "CAUTION – SKIN IRRITANT", "POTENTIAL SENSITIZER", and "Warning, contains the allergens egg and fish" have been included on the

principal display panel of the end-use product labels and "Severely irritating to the eye", "DO NOT get in eyes", "May irritate skin", "Avoid inhaling as a mist or dust on drying", and "May cause sensitization. DO NOT apply if allergic to eggs or fish. DO NOT apply if sensitive or allergic to garlic." have been included in the PRECAUTIONS section of the secondary display panel of both end-use product labels.

Because some individuals may be sensitive to eggs, fish, or garlic (for example, allergic), the statements, "Apply only when the potential for drift is minimal", "Individuals who are sensitive or allergic to eggs, fish, or garlic should avoid handling Bobbex Deer Repellent Concentrate and Bobbex Deer Repellent Ready-To-Use Spray" and "Individuals who are sensitive or allergic to eggs, fish, or garlic should avoid treated areas have dried or until after a heavy rain" have also been included in the PRECAUTIONS section of the secondary display panel of the product labels.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2012-33: Whole Egg Solids, Wintergreen Oil, Castor Oil, Fish Meal Mixture, Fish Oil Mixture, Garlic Oil, Meat Meal Mixture, Capsaicin and Related Capsaicinoids) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.